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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,605	12/04/2003	John F. Shanley	032304-089	6950

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,605	SHANLEY, JOHN F.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 04/24/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of Patent Number 6,241,762 has been reviewed and is accepted. The terminal disclaimer has been recorded.

2. The terminal disclaimer filed on 04/24/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of Patent Number 6,562,065 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 27, 38, and 50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 7, 11 and 16 of U.S. Patent No. 6,293,967 in view of Klein (USPN 5,922,020). The patent discloses an expandable medical device with a plurality of elongated beams joined together to form a cylindrical device (Claim 1, line 55) and a plurality of ductile hinges connecting the beams together (Claim 1, line 60). The hinge width is smaller than the beam width (Claim 1, line 62-64) so that the ductile hinges experience plastic deformation when the device is expanded (Claim 11, line 65-66). The patent does not explicitly disclose that the ductile hinges being are in the shape of a curved beam having first and second arcuate surfaces facing the same direction with the second arcuate surface being larger than the first. Klein discloses the limitations that are missing from the patent. Specifically, ductile hinges (42) in the shape of a curved beam along the hinge length having a first arcuate surface (the convex surface that is outlining part of opening 40 in Fig. 7A) and a second arcuate surface (the concave surface) that is longer than the first. During expansion, tensile strain is exhibited along the second longer arcuate surface.

5. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the curved hinges to ensure uniformity upon opening of the stent (Col 2, lines 39-40).

6. Claims 57-60 and 62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43, 46-48 of copending Application No. 10/231007 in view of Klein (USPN 5,922,020). Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending application discloses a cylindrical medical device that has first portions that function as strain concentration portions (ductile hinges) and second portions that function as lower strain concentration portions (elongated struts) and a plurality of holes that contain beneficial agent. The co-pending application does not disclose that the ductile hinges are asymmetric. Klein discloses the limitations that are missing from the patent. Specifically, asymmetric ductile hinges (42) in the shape of a curved beam along the hinge length having a first arcuate surface (the convex surface that is outlining part of opening 40 in Fig. 7A) and a second arcuate surface (the concave surface) that is longer than the first. During expansion, tensile strain is exhibited along the second longer arcuate surface.

7. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the curved hinges to ensure uniformity upon opening of the stent (Col 2, lines 39-40).

8. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

9. Claims 38, 50 and 57 are objected to because of the following informalities: The limitation "configured to reach a predetermined strain level upon a first percentage of expansion and to reach the predetermined strain level upon a second percentage of compression, wherein the first percentage is larger than the second percentage" is unclear. Appropriate correction is required. Although applicant has tried to clarify the claim limitation in the remarks dated 04/24/06, examiner asserts that the wording of the limitation needs to be further clarified. It is not clear what is the starting point or the initial diameter for the expansion and the compression that is being compared. For instance, are the expansion or compression forces being applied to the stent when it is fully closed? If so, how can it be further compressed? Do the terms "expansion" and "compression" in lines 10 and 11 refer to the hinges or to the stent as a whole? The term "strain level" is difficult to grasp in context with the claim language since it refers to deformation or compression. Perhaps, it would be clearer to refer to the stress applied to result in the different percentages of expansion and compression.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 27, 30, 32-34, 36-41, 44, 46-48, 50-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein (USPN 5,922,020).

12. Klein discloses a stent with a plurality of beams (32), each beam defining a width, and plurality of ductile hinges (42), each hinge defining a width, thickness and length. The hinge width is smaller than the beam width such that the hinge experiences plastic deformation when the device is expanded from a first to a second diameter. The hinges are in the shape of curved beams along their lengths having first and second arcuate surfaces with the second surface longer than the first. Referring to the marked up version below, the lines indicate the endpoints of each arc, which indicate the starting and ending points for measuring the surface of the arcs. It should be clear that the longer arcuate surface is the concave surface on the left side of the drawing. The curved beams are located so that during expansion of the device, tensile strain is distributed along the second arcuate surface as depicted below. Because the longer second arc will be in tension during expansion of the stent and will be in compression during compression of the stent, the percentage of expansion to reach the predetermined strain level will be more than the percentage of compression to reach the same strain level. The hinge width is at least 50% or 2/3 smaller than the beam width (Fig. 7A). There is an abrupt transition between the cross sectional area of the beams orthogonal to the beam length and the cross sectional area of the ductile hinges orthogonal to the hinge length that extends less than 10% of the length of the beam. The ratio of the length of the hinge to the length of the beam is less than 1:6. The ductile hinges are asymmetrical (Fig. 7a where the line of asymmetry goes from the top

of the figure to the bottom). The ductile hinges are configured so that upon compression during crimping, the strain will be distributed along the first arcuate surface and upon expansion, the strain will be distributed along the second arcuate surface (see below).

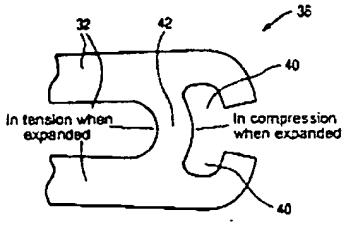

FIG. 7A

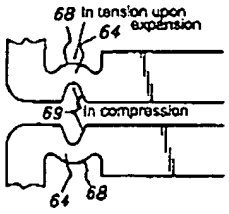

FIG. 3e

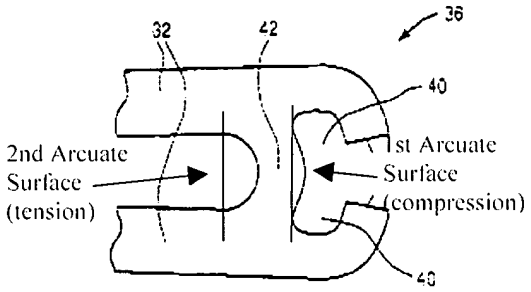

FIG. 7A

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 31 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Kusleika (USPN 5,722,979).

15. Klein discloses the claimed invention as stated above.

16. Klein does not disclose the device is expandable by a balloon.

17. Kusleika discloses a balloon catheter that is used to deliver stents where the balloon inflation pressure ranges from 2 to 6 atmospheres (Col 2, line 56-57 and Col 3 lines 28, 46, 62).

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a low pressure delivery balloon to deliver a stent in order to minimize potential medical complications such as balloon rupture, or damaging healthy tissue if the balloon is improperly placed (Col 1, lines 24-40). Kusleika offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

19. Claims 35, 49 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of MacGregor (USPN 4,994,071).

20. Klein discloses the claimed invention as stated above.

21. Klein does not disclose a beneficial agent for delivery to the patient.

22. MacGregor discloses that a stent can be coated with surface treatments to provide for the elution of drugs.

23. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate drug delivery into the stent. It is well known in the art to

deliver drugs to the stent site to prevent restenosis and or to heal diseased tissue. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

24. Claims 28, 29, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein.

25. Klein discloses the invention as stated above. Klein does not disclose that the hinge width is no greater than 60% of the hinge thickness.

26. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the hinge width smaller than the hinge thickness because Applicant has not disclosed that the hinge width being smaller than the hinge thickness provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with hinge width not being smaller than the hinge thickness because it would still be able to act as a deformable hinge to receive the strain during compression and expansion.

27. Therefore, it would have been an obvious matter of design choice to modify Klein to obtain the invention as specified in the claim.

28. Claims 35, 49, and 56-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Ndondo-Lay (USPN 6,273,908).

29. Klein discloses a device substantially as claimed as stated above except for the plurality of holes for containing a beneficial agent.

30. Ndondo-Lay discloses a stent that has a plurality of holes for delivering a beneficial agent. The holes are located on non-deforming elements or second portions with lower strain concentration. The beneficial agent is chemotherapy (Col 8, line 15-18) and the holes are laser-drilled (Col 9, line 59). Ndondo-Lay explains that devices for delivering drugs to a body portion during or after a medical procedure is ideal to prevent conditions such as thrombosis, restenosis, and tissue in-growth problems (Col 4, lines 7-21).

31. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of drug delivering holes onto a stent. Ndondo-Lay provides the motivation for using drug delivery holes in that they are beneficial for further treating diseased vessels and preventing restenosis. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

Response to Arguments

32. Applicant's arguments filed 04/24/06 have been fully considered but they are not persuasive. Applicant states that one of the differences between the device of the instant invention and the prior art of Klein is the orientation of the hinges and the stress-strain experience during expansion of the device. The rejection has been improved to clarify the examiners position. It should be clear that the longer arcuate surface is in fact

in tension when the stent is expanded as depicted in the instant claims and further clarified in the remarks.

33. Regarding the arguments to the double patenting rejection, examiner has more clearly stated the rejection above.

Conclusion

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
6/30/06